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10/786,681	02/25/2004	Shanta Modak	A34446-A-PCT-USA-AA	3011
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EXAMINER				
SAMALA, JAGADISHWAR RAO				
ART UNIT		PAPER NUMBER		
1618				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DL.NYDOCKET@BAKERBOTTS.COM

Office Action Summary

Application No.

10/786,681

Applicant(s)

MODAK ET AL.

Examiner

JAGADISHWAR R. SAMALA

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/02)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment and Request for Continued Examination filed on 03/23/2009.

Claims 3 and 4 have been added.

Claims 1-4 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/23/2009 has been entered.

Claim Rejections - 35 USC § 103

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jampani et al (US 6,022,551) and Modak et al (US 5,965,610) in view of Beilfuss et al (US 5,516,510) **are withdrawn** in view of amendment to claims.

However, further consideration, new ground(s) of rejection is made as discussed below.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Modak et al (US 5,965,610) in view of Beilfuss et al (US 5,516,510) and Osborne et al (US 5,906,808).

Modak discloses a composition comprising an anti-microbial agent and an anti-binding substance, which substantially prevents the irritant-inactivating agent from binding to the surface (e.g. soluble zinc compounds). The anti-microbial agents includes such as iodine, benzalkonium chloride, phenoxyethanol, triclosan, chlorhexidine digluconate (col. 5 lines 2-25), polyethyleneoxide surfactant, quaternary ammonium compounds such as amphoteric quaternary ammonium compounds, cationic substance used to block binding sites on the skin such as zinc acetate, zinc gluconate, zinc oxide, zinc stearate, and zinc salicylate (col. 7 lines 8-24) and the ratio of the ratio of the anti-microbial agent to the amount of the anti-binding substance (zinc salt) is preferably from about 1:13 to about 2:1 (col. 9 lines 2-6). Additional disclosure includes that composition can be used for rapidly inactivating microbial pathogens by application to a surface,

such as skin, wherein anti-microbial agent does not bind to the surface due to the inclusion of an anti-binding substance, allowing the anti-microbial agent to be released in tidal doses when a fluid contacts the composition.

Modak fails to include octoxyglycerin and an emulsifier in the composition therein.

Beilfuss discloses a composition comprising anti-microbial agents and glycerin monoalkyl ethers such as octoxyglycerin. The preferred anti-microbial agents include phenoxy ethanol, chlorhexidine salts, as well as salts of other cation-active compounds with deodorizing action (col. 3 lines 15-37). The glycerin monoalkyl ethers incorporated are mild and skin-compatible, have a good spreading capacity and confer a pleasant skin feeling, they are particularly suitable for deo-compositions. The glycerin monoalkyl ether, particularly 2-ethylhexyl glycerin ether (used in concentration in the range 0.01% to 20%) displays good antimicrobial effect, inhibits enzymes or catalysts which are responsible for the odor formation from the primarily odorless sweat, have an effect on the sweat-gland secretion, whereby sweat secretion is reduced. And further formulations were tested in the agar hole test for effectiveness against deo-germs i.e., gram (+) and gram (-) microorganisms (col. 4 table 1).

Osborne discloses a composition comprising about 0.65 and 0.85 wt.% of anti-microbial agent such as chlorhexidine or a pharmaceutically acceptable salt thereof and emulsifying wax such as Polawax A-31 (col. 2 lines 15-26). Osborne discloses that chlorhexidine and its salts are effective against wide range of Gram-positive and Gram-negative bacteria are known in the art (col. 1 line 17-20). This composition has

significantly improved and faster-acting antimicrobial properties and may be used in surgical scrubs and in wound dressings. Additional inert or antimicrobial active ingredients may be added to the composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate octoxyglycerin into Modak's composition. The person of ordinary skill in the art would have been motivated to make those modifications because it would allow a higher concentration of anti-microbial to make the composition more potent, and reasonably would have expected success because it was well known in the art that octoxyglycerin is highly compatible with anti-microbial agents (chlorhexidine) and support for the dispersing and co-emulsifying action in anti-microbial composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate emulsifier (Polawax) into Modak's composition. The person of ordinary skill in the art would have been motivated to make those modifications because incorporation Polawax into the composition would increase the effectiveness of the anti-microbial agent, and reasonably would have expected success because Polawax is a emulsifier (surfactant) and is a functional equivalent of the surfactant (polyethylene oxide) used in Modak's composition.

4. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jampani et al (US 5,980,925) in view of Cupferman et al (US 6,040,347) and Osborne et al (US 5,906,808).

Jampani discloses a composition comprising anti-microbial agent and anchoring agent (glycerine). The anti-microbial agent includes chlorhexidine or its derivatives such as chlorhexidine gluconate, chlorhexidine digluconate, bis-diguanides, bezalkonium chloride, polymeric quaternary ammonium compounds, and their combinations and derivatives. The effective amounts of anti-microbial agent present in range of about 0.1 to about 10% (abstract and col. 2 and 3). Additional active ingredients include zinc oxide (col. 5 line4 33-34). Additional disclosure includes that anti-microbial composition inhibits the growth of, or kills, organisms including bacteria, protozoans, viruses ... or other infectious agents and has increased substantive properties (synergistic effect) when combined with the anchoring agents (glycerine), meaning it penetrates into the skin providing long lasting anti-microbial activity even after wash off.

Jampani fails to include octoxyglycerin and an emulsifier in the composition therein.

Cupfermann discloses composition comprising octoxyglycerin for cleansing and caring for the skin (abstract). Octoxyglycerol is present in an amount ranging from 0.05 to 10% of total weight of the composition. Additional disclosure includes that the use of monoalkyl ethers of glycerol (octoxyglycerin), to act against pathologies related to *Propionibacterium acnes* and *Propionibacterium granulosum*, and in particular to treat seborrhea and acne.

Osborne discloses a composition comprising about 0.65 and 0.85 wt.% of anti-microbial agent such as chlorhexidine or a pharmaceutically acceptable salt thereof and emulsifying wax such as Polawax A-31 (col. 2 lines 15-26). Osborne discloses that

chlorhexidine and its salts are effective against wide range of Gram-positive and Gram-negative bacteria are known in the art (col. 1 line 17-20). This composition has significantly improved and faster-acting antimicrobial properties and may be used in surgical scrubs and in wound dressings. Additional inert or antimicrobial active ingredients may be added to the composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate octoxyglycerin into Jampani's composition. The person of ordinary skill in the art would have been motivated to make those modifications because incorporation of octoxyglycerin into the composition would provide the slow release of an active ingredient, such as an anti-microbial agent to inhibit the growth of, or kills, organisms, and reasonably would have expected success because Jampani's composition uses glycerin to enhance the activity of anti-microbial agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate emulsifier (Polawax) into Jampani's composition. The person of ordinary skill in the art would have been motivated to make those modifications because incorporation Polawax into the composition would increase the effectiveness of the anti-microbial agent, and reasonably would have expected success because Polawax is a emulsifier (surfactant) and is a functional equivalent of the glycerin (anchoring agent) used in Jampani's composition.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a

result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as adjusting the antiseptic potency or the intensity of the color. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Response to Arguments

Applicant argues that the reference does not suggest or describe the Sensiva (octoxyglycerin) can synergistically increase the effectiveness of benzalkonium chloride or chlorhexidine gluconate nor does the reference disclose that a quaternary ammonium compound (benzalkonium chloride) could be used in combination with glycerin monoalkyl ethers as an antimicrobial deo-active ingredient.

This argument is unpersuasive because synergism of the compounds is taught in prior art i.e., glycerin monoalkyl ethers (Sensiva) with other antimicrobial agents shows an increase in synergistic effects (Beilfuss, col. 3 lines 39-41). Further, Modak teaches the synergistic activity of BZK with PCMX (parachlorometaxyleneol, an antimicrobial agent) and CHX (chlorhexidine, see col. 6 lines 10-15). Therefore the combination of Sensiva with BZK and CHG would obviously results in synergistic effect and would promote the antimicrobial effects of a diverse array of compounds, including quaternary

ammonium compounds, chlorhexidine derivatives, biguanides, metal salts, antifungal azoles etc. Even though, prior art is silent about the synergistic effect of Sensiva, it known in the art(Burnier et al US 5,736,574), that Sensiva is known not to have any intrinsic antimicrobial activity and, this compound lacking in antimicrobial activity exhibited a synergistic effect on the antimicrobial activity of N-Octanoylglycine (antimicrobial agent, see col. 5 lines 13-19). Therefore combination of Sensiva with antimicrobial agent intrinsically would result in synergism and that combinatory immixture of at least one compound exhibiting antimicrobial activity and at least on one glyceryl monoalkyl ether (Sensiva) manifests a synergistic effect with regard to the antimicrobial activity of the combination. Applicant's are advice to show, how the instant claims are superior, combined to the prior art.

The skilled artisan would reasonably expected success in combining the prior art reference i.e., combining Sensiva with BZK and CHG and other antimicrobial agents, since the mechanism of synergistic action of Sensiva would enhance the antimicrobial effects particularly against gram(+) bacteria which are particularly relevant from the point of view of causing odor. "[A] person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." KSR international Co. v. Teleflex Inc., 82 USPQ2d 1385, 1390.

Applicant also argues that Modak specifically discloses synergists that may be used with chlorhexidine, it does not suggest or describe octoxyglycerin as such a synergist.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642,642 F.2d 413, 208 USPQ 871 (CCPA 1981; *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Modak's reference is relied upon to show that it is known in the art that anti-microbial synergist is meant to indicate a substance which in combination with an anti-microbial agent produces a microbiocidal effect greater than the added microbial effects of the substance and the anti-microbial agent used separately. Modak discloses that anti-microbial synergists contemplated for use in the composition include all anti-microbial synergists known to those of ordinary skill in the art, and Beilfuss reference is combined for its teaching of knowledge in the art of using Sensiva in combination with other antimicrobial agents to promote the antimicrobial effects of a diverse array of compounds.

Double Patenting

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 6, 24-25 and 29 of U.S. Patent No. 6,846,846 B2 (herein after '846) **are maintained** for reasons of record in the previous office action filed on 07/07/2008 and 12/23/2008.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr